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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,082	03/14/2005	Joseph D Mosca		5825

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PATENTIQUE PLLC
PO Box 5803
Bellevue, WA 98006

EXAMINER	
BLANCHARD, DAVID J	
ART UNIT	PAPER NUMBER
1643	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,082	MOSCA, JOSEPH D	
	Examiner	Art Unit	
	DAVID J. BLANCHARD	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 October 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,16-18,21,23 and 27-36* is/are pending in the application.

4a) Of the above claim(s) *28-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,16-18,21,23,27,35 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/27/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 6-15, 19-20, 22 and 24-26 are cancelled.

   Claims 1 and 17 have been amended.

   Claims 27-36 have been added.

2. Claims 1-5, 16-18, 21, 23 and 27-36 are pending.

3. This Office Action contains New Grounds of Rejections.

Election/Restrictions

4. This application contains claims directed to the following patentably distinct species of co-stimulatory molecules, e.g., newly added claims 27-34. The species are independent or distinct because the species are all structurally and functionally distinct, having different modes of operation and different effects. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, or a single grouping of patentably indistinct species, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

There is a search and/or examination burden for the patentably distinct species as set forth above because at least the following reason(s) apply:

- the species or groupings of patentably indistinct species have acquired a separate status in the art due to their recognized divergent subject matter
- the species or groupings of patentably indistinct species require a different field of search (e.g., searching different classes /subclasses or electronic resources, or employing different search strategies or search queries).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or a grouping of patentably indistinct species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species or grouping of patentably indistinct species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species or grouping of patentably indistinct species.

Should applicant traverse on the ground that the species, or groupings of patentably indistinct species from which election is required, are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing them to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

5. During a telephone conversation with Kawai Lau on 09 December 2010 a provisional election was made with traverse to prosecute the species of CD40 as the co-stimulatory molecule, claim 27. Affirmation of this election must be made by applicant in replying to this Office action.

6. Claims 28-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

7. Claims 1-5, 16-18, 21, 23, 27 and 35-36 are under examination. It is noted that claim 23 is drawn to a non-elected species, however, given that claim 23 was previously examined, the claim will continue to be under examination in view of the applied art below and in the interest of compact prosecution.

Information Disclosure Statement

8. The information disclosure statement (IDS) submitted on 27 September 2010 has been fully considered by the examiner. A signed copy of the IDS is included with the instant Office Action.

Rejections Maintained and New Grounds of Rejections

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. The rejection of claims 1-5, 16-18, 21, 23 and now applied to newly added claims 35-36 under 35 U.S.C. 102(b) as being anticipated by Mosca J. D. (WO 02/079396, published 10/10/2002) is maintained.

Mosca teaches methods for inducing an antigen-specific T cell mediated immune response for the treatment of cancer in a patient comprising administering a biological carrier preparation/whole virus particles that are totally inactivated and non-infectious, wherein the biological carrier preparation/whole virus particles comprise membrane fragments of the host cell or tumor cell (e.g., the host cell is either a tumor or non-tumor cell), wherein the tumor cell expresses at least one tumor antigen that is processed and bound to a host cell/tumor cell surface molecule that is an MHC class I or II surface molecule and wherein the biological carrier preparation/whole virus particles further comprises a co-stimulatory molecule, including B7-1 or B7-2 (see entire document, particularly pp. 4-5, 7-9, 12-14, claims and Figs. 1-2). Mosca teaches that tumor cells isolated from patients or established tumor-derived cells can be used as host for virus infections and the virus particles are harvested and inactivated, wherein the inactivated virus particles maintain their structure and can be used as a scaffold to carry cell surface expressed molecules (see pg. 14, lines 2-10, Fig. 2 and pg. 4, lines 1-5). Further, Mosca teaches

that the biological carriers can behave as antigen-presenting cells for the activation of T cell responses (pg. 12, lines 18-19) and thus, would necessarily mimic dendritic cells.

Thus, Mosca anticipates the claims.

Response to Arguments

The reply filed 10/25/10 points to pages 13-14 of the Mosca reference and states that the reference does not teach or suggest the use of a host cell that expresses an exogenous tumor specific antigen as required by the claims. Applicant also states that claim 21 is novel since the Mosca reference does not teach the use of a "non-tumor" cell. Applicant concludes that it is clear from the quote in Mosca (e.g., cited from pp. 13-14 of Mosca) that the document directs the skilled person to using a tumor cell, which endogenously expresses at least one tumor antigen. Applicants' arguments have been fully considered but are not found persuasive. Mosca at page 5, lines 25-26 teaches that the biological carriers may be prepared from cells isolated directly from the mammal (cells isolated from the tumor or of non-tumor source). Clearly Mosca teaches non-tumor host cells for the production of the biological carriers. Additionally at pp. 6 and 7 Mosca also teaches at least one exogenous antigen or antigen fragment on the biological carrier and wherein the exogenous antigen is a tumor antigen or is a tumor-specific transplantation antigen (hence, applied to newly added claim 36) (e.g., see pg. 6, lines 13-26 and pg. 7, lines 5-17 and claims at pp. 22-23). Thus, while it is correct that Mosca does teach the use of isolated tumor cells to produce the biological carrier, Mosca also clearly teaches the use of biological carriers that comprise at least one exogenous antigen or antigen fragment, wherein the antigen is a tumor antigen or is a tumor-specific transplantation antigen. Applicants' representation of the teachings of the Mosca reference are curious given that Mosca is also the inventor of the instant application and should be overly familiar with the teachings of the Mosca reference.

With respect to newly added claim 35, Mosca teaches that the biological carrier, which contain at least one exogenous antigen may be processed within immune cells and then presented by that immune cell to initiate an immune response, e.g., activation of T cell response (cell mediated immune response) (e.g., see pp. 12-14 and claims). Further, newly added claim 35 merely recites a consequence of the administration as taught by the prior art. Thus, the administration of the biological carriers, identical to those claimed, to cancer patients as taught

by Mosca, would necessarily result in the transfer of the exogenous tumor-specific antigen to an antigen-presenting cell in the cancer patient and would necessarily induce the effector cell mediated immune response against tumor cells in the cancer patient. Merely discovering and claiming a new benefit of an old process cannot render the process again patentable. Verdegaal Bros., Inc. v. Union Oil Co. of Calif., 814 F.2d 628, 632-33, 2USPQ2d 1051, 1054 (Fed. Cir.), cert. Denied, 484 U.S. 827 (1987).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 1 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mosca J. D. (WO 02/079396, published 10/10/2002, cited on PTO-892 mailed 6/25/10) in view of Alexandroff et al (Molecular Immunology, 37(9):515-526, 2000).

The teachings of Mosca are described supra. Mosca does not specifically teach wherein the biological carrier preparation/whole virus particles further comprises the co-stimulatory molecule CD40. This deficiency is made up for in the teachings of Alexandroff et al.

Alexandroff et al teach that the co-stimulatory molecule CD40 is expressed on cancer cells and interaction with its ligand (e.g., CD40L) results in the secretion of a number of

cytokines and induction of apoptosis and cell growth arrest and is an important factor in the generation of tumor-specific T cell responses (see entire document, particularly pp. 515-516, 52—521, 523 and Tables 4-7).

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to have produced a method of inducing an antigen-specific T cell mediated immune response for the treatment of cancer in a patient comprising administering a biological carrier preparation/whole virus particles that are totally inactivated and non-infectious, wherein the biological carrier preparation/whole virus particles comprise membrane fragments of the host tumor cells, wherein the host tumor cells express CD40 and at least one exogenous tumor antigen that is processed and presented by an MHC class I or II for therapeutic benefit in cancer patients.

One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success at the time the invention was made to have produced a method of inducing an antigen-specific T cell mediated immune response for the treatment of cancer in a patient comprising administering a biological carrier preparation/whole virus particles that are totally inactivated and non-infectious, wherein the biological carrier preparation/whole virus particles comprise membrane fragments of the host tumor cells, wherein the host tumor cells express CD40 and at least one exogenous tumor antigen that is processed and presented by an MHC class I or II for therapeutic benefit in cancer patients in view of Mosca and Alexandroff et al because Mosca teaches methods for inducing an antigen-specific T cell mediated immune response for the treatment of cancer in a patient comprising administering a biological carrier preparation/whole virus particles that are totally inactivated and non-infectious, wherein the biological carrier preparation/whole virus particles comprise membrane fragments of the host cell or tumor cell wherein the tumor cell expresses at least one tumor antigen that is processed and bound to a host cell/tumor cell surface MHC molecule and wherein the biological carrier preparation/whole virus particles further comprises a co-stimulatory molecule and Alexandroff et al teach that the co-stimulatory molecule CD40 is expressed on cancer cells and interaction with its ligand (e.g., CD40L) results in the secretion of a number of cytokines and induction of apoptosis and cell growth arrest and CD40 is an important factor in the generation of tumor-specific T cell responses. Therefore, one of ordinary skill in the art at the time the invention was

made would have been motivated to modify the method of Mosca by expressing CD40 on the tumor cell surface, since Mosca explicitly suggests that the "tumor cells can be in addition modified on their surface with co-stimulatory molecules or other accessory molecules that would facilitate the biological carrier's ability to mount an immune response against the tumor", and according to Alexandroff et al the CD40-CD40L interaction induces apoptosis and cell growth arrest and CD40 is an important factor in the generation of tumor-specific T cell responses. The strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. In re Sernaker, 702 F.2d 989, 994-95, 217 USPQ 1, 5-6 (Fed. Cir. 1983). Thus, it would have been prima facie obvious to one skilled in the art at the time the invention was made to have produced a method of inducing an antigen-specific T cell mediated immune response for the treatment of cancer in a patient comprising administering a biological carrier preparation/whole virus particles that are totally inactivated and non-infectious, wherein the biological carrier preparation/whole virus particles comprise membrane fragments of the host tumor cells, wherein the host tumor cells express CD40 and at least one exogenous tumor antigen that is processed and presented by an MHC class I or II for therapeutic benefit in cancer patients in view of Mosca and Alexandroff et al.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

13. No claim is allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Misook Yu, can be reached at (571) 272-0839.

The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David J. Blanchard/
Primary Examiner, A.U. 1643